

REMARKS

Amendment Of The Claims

Claim 6 is amended to clarify the active steps utilized. In particular, the claim now recites as its result that an antiserum that specifically binds to antigen-stimulated lymphocytes is obtained. Furthermore, the claim is amended to clarify that that animal used in the second immunization is of the same genetic line as the animal used in the first immunization. This is clear, because the fetus used for obtaining cells for the second immunization is of the same genetic line as the animal used in the first immunization and so the "same genetic line" is the same in both of these steps.

The term "intact organs" is amended to "whole organs" to resolve the logical inconsistency between use of cells and intact organs pointed out by the Examiner. The formation of a suspension of cells of the intact organs and the serum from the second immunization is added to provide antecedent basis for such in the next step as recited and is supported by the original claim 1 of the application.

The limitation that the animal utilized in the immunization process for obtaining the antiserum is not a human being is removed in view of the Examiner's insistence that such negative limitation is not supported by the specification. New claim 12 recites that the animal used is a "rodent", consistent both with

the typical use of rodents for raising of antibodies in the art of immunology and the illustrative example utilizing rats for immunization that is disclosed in the specification. New claim 13 is directed to scope admitted by the Examiner to be described and enabled.

Rejections under 35 USC § 112, second paragraph

Claims 6-11 stand rejected under 35 USC § 112, second paragraph, for alleged indefiniteness for the reasons pointed out at pp. 2-3 of the Office Action. Applicants submit that the amendments to claim 6 made herein obviate those grounds of rejection.

Rejection under 35 USC § 112, first paragraph - written description

Claims 6-11 stand rejected under 35 USC § 112, first paragraph, for alleged lack of written description in the specification of the limitation in claim 6 that the animal used in the immunization, and from which fetal cells are obtained, is not a human being. This limitation is struck from the claims, thus obviating this rejection.

Rejection under 35 USC § 112, first paragraph - enablement

Claim 11 is rejected under 35 USC § 112, first paragraph, for alleged lack of enabling disclosure in the specification. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner fails to make a *prima facie* case of lack of enablement. The Examiner merely alleges that the specification does not enable use of animals other than a rat for the immunization steps for obtaining the antiserum reagent, or for use of a sample other than a blood sample obtained from a human.

It is the burden of the Examiner to establish *prima facie* lack of enablement. Enablement is a question of whether or not undue experimentation is required to practice the claimed invention, and the is question is considered by weighing of eight different factors as set forth in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). All of these factors must be considered, and so the Examiner's conclusion of lack of enablement, being based only upon the breadth of the claims, is legally deficient.

Furthermore, the Examiner's assertion that a blood sample must be used because the specification only describes use of an erythrocyte sedimentation test is not correct. While the working example set forth describes use of an ES test, the more general disclosure describes that immunofluorescent assay may be utilized. See, page 4, line 26.

Furthermore, the Examiner should note that claim 11 in fact recites that an ES test is used for the diagnosis; it is claim 9 that is more broadly generic.

For all of the above reasons, the rejection of claim 11 under 35 USC § 112, first paragraph for alleged lack of enabling disclosure in the specification should be withdrawn.

Rejection for lack of novelty

Claims 6-11 stand rejected under 35 USC § 102(a) as being anticipated by Erkov et al, WO 97/22881. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The present invention is distinct from what is disclosed in Erkov '881 at least in that the specific method steps recited in claim 6, and claims dependent thereon, are not disclosed in the reference. Thus, at least claims 6-8, 12 and 13, directed to a method for raising an antiserum of the invention are not anticipated by Erkov '881.

Furthermore, for a reference to be novelty-destroying, it must enable the practice of the invention that is claimed. Applicants submit that the Erkov '881 reference is deficient in this regard, as it fails to disclose how to raise an "antiidotypic antiembryonic" antiserum of the present invention. Accordingly, Erkov '881 cannot serve as a novelty-destroying

reference as to the instant claims 6-13 and the instant rejection should be withdrawn.

Rejection for obviousness

Claims 6-10 stand rejected under 35 USC § 103(a) as being unpatentable over Erkov, Klinicheskaya Meditsina (1995) in view of Erkov Voprosy Onkologii (1991). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that the Examiner fails to establish *prima facie* obviousness of the claimed invention. In particular, the combination of the cited references fails to disclose or suggest all of the limitations set forth in the rejected claims.

As explained above in relation to Erkov '881, neither Erkov (1995) nor Erkov (1991) disclose how to produce and "antiidotypic, antiembryonic" antiserum. Accordingly, no combination of these references discloses or suggests the active steps recited in claim 6, or in claims dependent thereon. Therefore, the instant rejection must be withdrawn.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of

the pending claims and passage of the application to issue is respectfully requested.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a two (2) month extension of time for a small entity for filing a response in connection with the present application. The required fee of \$215.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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